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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,679	08/18/2003	Xavier Paliard	PP01612.009 (2300-1612.10	4593

27476 7590 09/11/2008

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,679	PALIARD ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-32,37-40,42,45 and 46* is/are pending in the application.

4a) Of the above claim(s) *23-32,37-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The response and amendment filed on 07/07/08 has been acknowledged. Claims 23 and 45-46 have been amended. Claims 1-22, 33-36, 41, and 43-44 were canceled. Claims 23-32, 37-40, 42, 45-46 are pending. Claims 23-32, 37-40 and 42 were withdrawn from consideration. Claims 45-46 are considered before the examiner.

Double Patenting

1. The obvious double patenting rejection over 45 and 46 has been withdrawn after further considering the conflict claims in the copending Application SN. 10,281,341. The conflict claims of the copending Application No. 10,281,341 is directed to an immunogenic composition comprising HCV E1/E1 envelope proteins in addition to HCV NS3, NS4, NS5a, NS5b and core antigen polypeptides. Claims 45 and 46 in the current Application is directed to a composition comprising HCV polypeptides, wherein the polypeptides consist of HCV NS3, NS4, NS5a, NS5b and core antigen polypeptides.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The rejection of claims 5 and 8 under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (Vaccine 1999, Vol. 17, pp. 1136-1144) and Lagging et al. (J. Virol. 1995, Vol. 69, No. 9, pp. 5859-5863) or Geissler et al. (J. Immunol. 1997, Vol. 159, pp. 5107-5113) has been removed since claims 5 and 8 have been canceled by Applicants' amendment.

4.

5. Claims 45 and 46 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (WO 96/38474A2), Beld et al. (Hepatology 1999, pp. 1288-1298) and Valenzeula et al. (WO 97/44469A2).

6. Applicants argue that the claimed invention as amended is an unexpected result as shown in Example 12 and Fig. 2 in the specification. The cited references fail to provide any evidence that a composition comprising mixture of individual HCV polypeptide of NS3, NS4 and NS5a, NS5b and core polypeptide would be particular effective for immunizing against HCV. In addition, there can be no reasonable expectation of success that compositions comprising the particular combinations of HCV antigens would be effectively in immunizing against HCV based on the teachings of these references. Applicants further cite that FDA requires the efficacy of an immunogenic composition comprising mixture of antigens be shown even if the efficacy each of the individual components has already been demonstrated because of unpredictability already obtaining effective immunity of mixed antigen vaccines cannot be predicted.

7. Applicants' argument has been fully considered. However, it is not found persuasive to withdraw the rejection. Because the example 12 and Fig. 2 have only shown that when the DNA vaccines are formulated with the antigen carrier/adjuvant PLG, a mixture of plasmid comprising individual plasmid encoding NS3, NS4, NS5a, and NS5b polypeptide respectively can produce an unexpectedly higher immune response than that produced by using one plasmid encoding HCV NS3, NS4, NS5a, NS5b as one fusion protein. There is no any evidence approving that a composition comprising NS3, NS4, NS5a, NS5b and core antigen polypeptides as a mixture can produce an unexpectedly higher immune response than that using a fusion protein encoding NS345ab and core fusion protein. It is well known in that mechanisms of the immune response inductions by a DNA molecule and a protein are different. They are considered to be patentably distinct each from other in the art and in the instant Application family too.

8. Because prior to the current Application was filed, each individual HCV protein/polypeptide antigen of NS3, NS4, NS5a, NS5b and core had already been approved to be immunogenic, absence an evidence to the contrary, the claimed invention as a whole is still prima facie obvious absence unexpected results. The rejection is therefore, maintained.

9.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li, M.D/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648